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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,796	06/07/2001	Kathleen L. Horwath	RB-125 SEQ	9032

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,796

Applicant(s)

HORWATH ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/1/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Applicant's election of Group II (Claims 27-37) in the reply filed on November 18, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-40 are pending. Claims 27-37 are under examination. Claims 1-26 and 38-40 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Specification

3. The specification is objected to because of the following informalities:
 - (a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademark such as BLUESCRIPT®, for example, has been noted in this application (see page 21). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

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- (b) The specification is objected to because on page 14, line 11, no period appears at the end of the sentence (see "be found in FIG. 1.0").
- (c) The specification is objected to because on page 20, line 1 and throughout the specification, the sequence notation is improper; see for example "SEQ. ID No.1" which should be "SEQ ID NO:1".
- (d) On page 16, line 39 of the instant specification, the word "activator" is misspelled as "activitor".

Correction of the above and compliance with the sequence rules is required.

Abstract

- 4. The abstract is objected to because of the following informalities:
The first and second sentence of the abstract lacks a verb and object.
Correction is required.

Drawing

- 5. The drawings are objected to because Figure 2.6c has a typographical error, see "A: Mature Tm 13.17 amino acid r sidure", which should be "A. Mature Tm 13.17 amino acid residue". In addition, Figure 2.6c discloses amino acid sequences without the corresponding sequence notation, for example "SEQ ID NO:". See also Figure 4.3 where the following labels appear that are inconsistent, "A. and B", which should be "A. and B.". Note that Figures 2.10, 2.12, 4.6 a-b, 4.13-4.14, 4.16-4.18, 8.43 and 8.44 do not recite the sequence identifiers that correspond to the sequence presented in the

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alignment. For consistency Figures 7 (1-3) should be disclosed as "7.1; 7.2 and 7.3" instead of "7-1" etc. Figure 8 has parts A-F, which are not described in the specification. There is no Figure 8.1 *per se*, just Figures 8.1A and 8.1B. Figure 8.37 has parts A and B, which are not described. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

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6. The Information Disclosure Statement filed on November 1, 2002 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for providing antifreeze or recrystallization inhibition properties to a subject formulation, does not reasonably provide enablement for said method wherein the polynucleotides for the activated protein are used to create transgenic or gene-modified plants, crops, fish or animals having greater tolerance to cold climatization. The specification is not enabled for all transgenic cells and organisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement

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refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue.

These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass a human being or other mammals/whole organisms that are not supported by the instant specification. The claim encompasses the creation of a transgenic organism or animal or mammal including a human being having a greater tolerance to cold climatization via gene therapy methods. The instant specification and the art generally provides support for fish, plants, foods for example, however, does not provide support for creating a human being that has a greater resistance to cold climatization. There is no demonstration or evidence provided in the instant specification to transgenically create such a human. The instant specification and claims disclose transgenic cells and organisms, which reads on an *in vivo* environment. The disclosed transgenic cells/organisms/animals reads on a whole animal and therefore a human being, and the instant claim 37 is not enabled for the full

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scope. In view of the foregoing, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

Predictability of the success of creating a whole organism/animal such as a human being that has a greater tolerance for cold climates is not supported by the art or the instant specification.

The state of the prior art provides evidence for the high degree of unpredictability as stated above. For example, Eliot (Science, vol. 269 (5227), pages 1050-55, 1995) indicates that gene therapy has more than 100 clinical trials with millions of dollars invested, however is struggling to meet the expectations and that a product realistically is far off. The Eliot reference indicates that while there is support for gene therapy and several reports of gene transfer and expression there is still little or no evidence of therapeutic benefits in patients or even in animal models (page 1050). As there is no analogous art, the specification needs to provide adequate guidance/direction to enable the skilled artisan to practice the claimed invention commensurate in scope with the claims.

The working examples provided do not rectify the missing information in the instant specification as the claims broadly read on a human being which is neither exemplified in the specification or the prior art. Thus, one of skill in the art would have to engage in undue experimentation to practice the claimed invention commensurate in scope with the claims.

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The issue in this case is the breath of the claim in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Therefore, for all these reasons the claimed invention is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 27-37 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 27 is confusing for the recitation of "a subject formulation to thermal hysteresis", it is suggested that the claim is amended to recite "a subject formulation to obtain thermal hysteresis". The dependent claims hereto are also included in this rejection because they do not rectify the deficiency in claim 27.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 27-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubinsky et al. (U.S. Patent No.5,358,931, October 25, 1994).

Rubinsky et al. teach methods of formulation and use of thermal hysteresis proteins that offer benefits by imparting the preservation and improved viability of cell suspensions, tissues and whole organs by achieving antifreeze properties (see abstract and column 2), said proteins in concentrations of 1mg/mL or more (claim 27, see column 10). Rubinsky et al. disclose freezing point depression in a non-colligative manner (claim 28, see columns 2-3). The method of Rubinsky et al. is directed to plant cells, plant seeds and whole plants (claim 31, column 4 of the patent). In addition, Rubinsky et al. teach cryopreservation of target tissues (claim 32, see column 5) and hypothermic exposure (claim 33, see column 14). Claim 34 is anticipated because Rubinsky et al. teach a method that protects the cell or a whole organism such as a plant (claim 35) under adverse conditions such as the formation of ice crystals (claim 34), see columns 3-4. Rubinsky et al. disclose that their invention has application in the preservation of foods, which would otherwise lose their appeal due to the breakdown of

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cell structures and functions in the foodstuffs (claim 36, column 4). Therefore the limitations of the claims are met by the reference.

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS. *HR*

Patent Examiner *2/1/05*

Jon Weber
JON WEBER
SUPERVISORY PATENT EXAMINER